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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,944	03/22/2001	Keith D. Allen	R-654	8251

26619 7590 01/13/2005

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EXAMINER	
QIAN, CELINE X	
ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/815,944	ALLEN ET AL.	
	Examiner	Art Unit	
	Celine X Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30,32 and 33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,32 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 30, 32 and 33 are pending in the application.

This Office Action is in response to the Amendment filed on 10/7/04.

Response to Amendment

The rejection of claims 30, 32 and 33 under 35 U.S.C.112 1st paragraph is maintained for reasons set forth of the record mailed on 6/3/04 and further discussed below.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 32 and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicant argues that the examiner's conclusion regarding the ability of the skilled artisan to use the claimed invention is not consistent with the rules regarding the utility of an invention because the claimed invention has a well-established utility. Applicant assert that the skilled in the art would immediately appreciate how to use a knockout mouse because any knockout mouse has the inherent and well-established utility of defining the function and role of the disrupted gene regardless of specific phenotypes, characterizations or properties of the knockout mouse. Applicant further cites a passage at NIH website which

indicate that knockout mice represent a critical tool in studying gene function. Furthermore, Applicants indicates that the claimed invention is purchased by three largest pharmaceutical companies, thus such commercial acceptance supports Applicant's position that one skilled in the art would know how to use the knockout mouse. Further, Applicant asserts that the examiner has stated that one of ordinary artisan would have been motivated to produce the melanocyte stimulating hormone receptor knockout mouse to study the precise role of melanocyte stimulating hormone receptor plays in cell proliferation and inflammatory response in the 103 (a) rejection previously, and such statement is an admission that the skilled artisan would know how to use the claimed invention to determine the function of a gene. Applicant also asserts that the claimed invention is useful for a particular purpose, to further study the role of melanocyte stimulating hormone receptor in activity related disorders such as ADHD or Parkinson's disease in light of the observed phenotype of hypoactivity in an open field. Lastly, Applicant argues that the utility of the claimed inventions does not depend on a correlation between the disclosed phenotype and a disease in human for the enablement of the claimed invention. Applicant cites Zimmer et al. to demonstrate that transgenic mice are well-established tool in drug discovery regardless of phenotype. Applicant also argues that the disclosed phenotype of hypoactivity is related to a disorder or condition may be observed in human such as hyperactivity and ADHD. Applicant asserts that usefulness in patent law necessarily includes the expectation of further research and development according to *In re Brana*. Applicant thus concludes that the claimed invention is enabled fully by the instant specification.

These arguments have been fully considered but deemed unpersuasive. The reasons for the non-enablement rejection were discussed in detail in the office action mailed on 6/3/04. In

response to Applicant's response regarding any knockout mouse has a well-established utility, the examiner does not agree with Applicant's assertion that the claimed invention has a well-established utility. Applicant is reminded that in MPEP, the guideline for the utility requirement clearly states: "An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible." In the instant case, the utility that applies to any knockout mouse is not specific to the claimed invention, the melanocyte stimulating hormone receptor knockout mouse. Applicant's assertion that the claimed mouse is useful to study the function of melanocyte stimulating hormone receptor is an invitation for further research on the claimed invention in which the function of said invention Applicant clearly does not know.

In response to Applicant's argument of the commercial sale of the claimed mouse, Applicant is reminded that the sale of a product does not automatically gives the product patentable use according to the statue of 35 U.S.C.101 and the utility guideline set forth in the MPEP. Commercial success is only considered as secondary evidence for overcoming a 103 (a) rejection according to guidelines set by MPEP. If Applicant considers the sale of the claimed invention proves the utility and teaches specifically how to use the claimed invention, Applicant is invited to provide case law that validate such statement.

The examiner's statement in the previous 103 rejection was directed to claims with different scope, and this rejection was withdrawn when the claims are amended to the current scope. This statement cannot be relied on for the enablement of the instant claimed invention because it merely provides a reason for making a melanocyte stimulating hormone receptor

knockout mouse of entirely different scope (without the limitation of the instantly claimed phenotype). The statue requires the specification to teach not only how to make but also how to use the claimed invention in such a way that undue experimentation is not required. The specification teaches that the claimed mouse can be used as model for disease or drug screening model. However, the specification fails to teach what type of disease the claimed invention can represent. The specification also fails to teach what type of drug such mouse can screen. As such, the melanocyte stimulating hormone receptor knockout mouse with claimed phenotype is not a valid model for any human disease. The examiner cannot agree with Applicant's assertion that the disclosed phenotype of hypoactivity is correlated with a disorder that is observed in humans because such genotypic and phenotypic correlation as claimed is not known in any human disorder. Applicant gives the example that hypoactivity is related to ADHD, Parkinson's disease, and hyperactivity. However, the prior art teaches that these disorder are caused by multiple factors which have nothing to do with the function of melanocyte stimulating hormone receptor gene. Moreover, contrary to Applicant's assertion, ADHD, Parkinson's and hyperactivity patients do not display hypoactivity behavior. It is unclear what kind of "hypoactivity" Applicant is referring to in such patients that the mouse model can represent. As such, the claimed mouse cannot be a valid model of such disorders just because it exhibits the phenotype of hypoactivity in open field test. The specification fails to teach how to use the claimed mouse according to the disclosed embodiment of being a disease mouse. Therefore, the specification fails to enable the claimed invention.

In response to Applicant's argument based on Zimmer et al., Applicant is reminded that the claimed mouse and mice disclosed in the reference are different products because they have

different genotype and phenotype. In addition, the CB1 gene that is knocked out in the reference has well studied functions in CNS related to locomotive activity, whereas the specification does not teach specific function for the melanocyte stimulating hormone receptor in CNS and locomotive activity. As such, Zimmer et al. do not give the claimed mouse a patentable utility.

In response to Applicant's argument regard *In re Brana*, the examiner does not agree that it applies in the instant case. Applicant has taken one conclusion out of the context. Although the case law states "Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development," it is referring to a chemical compound for its anti-tumor activity which has been demonstrated in tumor cell line. The specification of that application has taught a substantial and specific use for the claimed compound. However, in the instant case, the claimed knockout mouse does not have a specific and substantial use since the specification does not teach credibly what disease model the claimed mouse represents and/or what type of drug the claimed mouse can screen. As discussed above, the utility of studying the function of the melanocyte stimulating hormone receptor is an invitation of further research in which the function of the claimed invention is not known. Therefore, one skilled in the art would not know how to use the claimed invention according to the embodiments disclosed by the instant specification. The rejection is thus maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636

DAVE TRONG NGUYEN
PRIMARY EXAMINER